

February 7, 2000

Dockets Management Branch (HFA-305)
FDA
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: DOCKET # 99D-5347

**PRECAUTIONERY MEASURES TO REDUCE THE POSSIBLE RISK OF
TRANSMISSION OF ZOONOSSES BY BLOOD AND BLOOD PRODUCTS FROM
XENOTRANSPLANTATION PRODUCT RECIPIENTS AND THEIR CLOSE
CONTACT**

To whom it may concern:

The proposed guideline to "indefinitely defer" blood donations from xenotransplantation recipients, their close contacts, and relevant clinical personnel is inadequate to protect the U.S. blood supply.

In order to prevent the recipients (patients), their close contacts and health care personnel from donating blood a national database listing names and addresses must be maintained. Such a database, however, is not foolproof. It cannot be legally enforced, it would require significant funds to develop and administer and it is subject to human error and/or changes in personal status of the recipients, their close contacts and clinical personnel involved.

Also, the proposed guidelines ignore the fact that some viruses are latent, and many may be transmitted like a common cold. They may manifest themselves years or decades after infection. The potential consequences for the U.S. blood supply are frightening.

The unknown consequences associated with xenotransplantation need to be taken into account when forming policy. It is the FDA's responsibility as an institution of the United States government to protect the blood supply and the lives of it's citizens by BANNING xenotransplantation immediately.

Regards,

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